

DATE: September 21, 2000

TO: Medicare + Choice Organizations

SUBJECT: Coverage of Clinical Trials

I would like to inform you about an important new initiative that President Clinton has recently announced which will encourage many more seniors and people with disabilities to participate in clinical trials by ensuring that Medicare will pay for most of the cost of beneficiary participation in clinical trials. This initiative will require a change in coverage policy for Medicare+Choice organizations. On September 19, 2000, the Health Care Financing Administration published a National Coverage Determination (NCD) regarding coverage of certain benefits related to clinical trials. The full text of this NCD is attached.

As of September 19, 2000, Medicare will cover certain benefits related to clinical trials. The cost for covering these benefits was not included in M+C organization capitated payment rates, and the costs were high enough to meet the threshold for "significant cost" under 422.109. Medicare will, therefore, be paying for these services outside of the M+C capitated payment rate until these costs are reflected in M+C payment rates. Medicare intermediaries and carriers will be making payments directly to providers of clinical trials services.

We also released a Program Memorandum related to this initiative to our carriers and intermediaries on September 19, 2000, which is also posted on our website and attached for your review. This memorandum provides interim instructions for claims processing for fee-for-service and Medicare+Choice beneficiaries. Carriers and intermediaries will notify fee-for-service providers of these processes.

We will be providing you with more detailed information through an operational policy letter (OPL) regarding the coverage of clinical trials in the next several days. In this OPL, we will address issues such as: clinical trial services that qualify for coverage, payment procedures, provider enrollment, beneficiary cost-sharing, and notification requirements. In addition to the OPL, we are currently developing questions and answers on the implications of this NCD on M+C plans. When these are finished, they will be posted with the NCD and program memorandum at www.hcfa.gov/quality/8d/htm.

We understand that this initiative may raise concerns for you. We hope to implement this initiative without any major disruption to your organization and beneficiary services. To that end, we will continue to work with the managed care industry to ensure a smooth implementation plan.

Robert A. Berenson, M.D., Director
Center for Health Plans and Providers